



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 403

CMS-6076-IFR2

RIN 0991-AC0

Adjustment of Civil Monetary Penalties for Inflation; Correcting Amendment

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule; correcting amendment.

SUMMARY: In the September 6, 2016 **Federal Register** (81 FR 61538), we published an interim final rule (IFR) issuing a new regulation to adjust for inflation the maximum civil monetary penalty amounts for the various civil monetary penalty authorities for all agencies within HHS. This correcting amendment corrects a limited number of technical and typographical errors identified in the CMS provisions of the September 6, 2016 IFR.

DATES: Effective date: This correcting amendment is effective [Insert date of publication].

Applicability date: The corrections indicated in this correcting amendment are applicable beginning September 6, 2016.

FOR FURTHER INFORMATION CONTACT:

Ian Mahoney, (410) 786-4247.

SUPPLEMENTARY INFORMATION:

I. Background

In the September 6, 2016 (81 FR 61538) **Federal Register**, in the interim final rule (IFR) titled "Adjustment of Civil Monetary Penalties for Inflation," there is a

technical error identified and corrected in this correcting amendment. The provisions of this correcting amendment are effective as if they had been included in the IFR published on September 6, 2016 and, accordingly, are applicable beginning September 6, 2016.

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) (section 701 of the Bipartisan Budget Act of 2015, Pub. L. 114–74, enacted on November 2, 2015), which amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) (Pub. L. 101–410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461 note 2(a)), is intended to improve the effectiveness of civil monetary penalties and to maintain the deterrent effect of such penalties by requiring agencies to adjust the civil monetary penalties for inflation on an initial basis and annually. The U.S. Department of Health and Human Services (HHS) lists the civil monetary penalties and the penalty amounts administered by all of its agencies in tabular form in 45 CFR 102.3.

II. Summary of Errors

On page 61561 of the IFR, in the table indicating the changes in regulations text for § 403.912(a)(1), we inadvertently made errors in the specifying the minimum and maximum civil monetary penalty amounts to which the inflation adjustment would be applied (the “base penalty range”). Specifically, we inadvertently changed the base penalty range from \$1,000 and \$10,000 to \$10,000 and \$100,000, respectively. The statutory authority for this civil money penalty is section 1128G of the Act (42 USC 1320a-7h), which requires applicable manufacturers to report annually to CMS any payments or other transfers of value to covered recipients. In addition, the statute requires applicable manufacturers and applicable group purchasing organizations to

report annually to CMS ownership investment interests held by physicians or their family members in such entities. Section 1128G(b)(1) of the Act provides that if an applicable manufacturer or applicable group purchasing organization fails to report the required information in timely manner to CMS, the entity is subject to a civil money penalty amount between \$1,000 and \$10,000 for each payment or transfer of value or ownership or investment interest not reported, up to an annual maximum of \$150,000 per submission by a reporting entity. Accordingly, we are revising § 403.912(a)(1) to correct the typographical error in the penalty ranges originally established in section 1128G of the Act.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

In accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)), we ordinarily publish a notice of proposed rulemaking in the Federal Register to provide for a period of public comment before the provisions of a rule take effect. However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the notice. Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

We believe that this document does not constitute a rulemaking that would be subject to the requirement for a public comment period. Specifically, we find that

undertaking further notice and comment procedures to correct the IFR in unnecessary and contrary to public interest.

First, we believe it is unnecessary to allow for public comment regarding whether to correct a misstated penalty range that is inconsistent with, and exponentially higher than, that permitted by the authorizing statute. As noted previously, this correcting amendment merely corrects a typographical error in the base penalty range to which the inflation increase implemented by the IFR would be applied. This correction is necessary to ensure that the base penalty range does not exceed the range authorized under section 1128G(b)(1)(A) of the Act, as adjusted under the Inflation Adjustment Act. Public comment on this correction amendment is unnecessary because it could never change the statutory penalty range at issue. We note that the IFR never indicated that we were increasing the base penalty range identified in this or any other civil money penalty authority. In fact, on page 61548 of the IFR, we indicated that the new inflation adjusted penalty range under § 403.912(a) would be from \$1,087 to \$10,874 per unreported arrangement, up to a calendar year cap of \$163,117. Furthermore, we note that the erroneous base range stated on page 61561 of the IFR makes little sense in light of the statutory calendar year cap for this penalty. Under the original base penalty range, CMS could impose the minimum penalty of \$1,000 for up to 150 unreported arrangements. Under the erroneous regulations text in the IFR, CMS would be permitted to impose the minimum penalty amount of \$10,000 for only a maximum of 16 unreported arrangements. Even if we had the statutory authority to increase the base penalty range through rulemaking, the maximum penalty amount erroneously stated in the IFR is patently inconsistent with one of the stated policies of the IFR-- to maintain the deterrent

effect of civil money penalties. Second, we believe that providing an opportunity for public comment on this correcting amendment is contrary to the public interest. First, as noted previously, public comment in this case could never change the statutory penalty range at issue. We believe that it would not be in the public interest to offer a futile comment period. Second, the entities subject to civil money penalties authorized under section 1128G(b) of the Act should be advised, in a timely manner, of the correct amounts for which they could be liable. It is in the public interest to ensure that the regulations accurately reflect the statutory authority.

For similar reasons, we are also waiving the 30-day delay in effective date for this correcting amendment. First, we believe it is unnecessary to delay the effective date of corrections to a typographical error in regulation text that was patently inconsistent with the relevant statutory authority. Second, we believe that delaying the effective date of these corrections would be contrary to the public interest because the entities subject to civil money penalties should be advised, in a timely manner, of the correct amounts for which they could be liable. Therefore, we find good cause to waive the 30-day delay in effective date.

Finally, the corrections indicated in this correcting amendment are applicable to civil monetary penalties as if they had been included in the IFR. That is, the corrections are applicable to civil money penalties imposed under §403.912(a)(1) beginning September 6, 2016, the date the IFR became effective. We do not believe this correcting amendment constitutes retroactive rulemaking because the erroneous base penalty range was never authorized under section 1128G(b) of the Act. In addition, we have not imposed any penalties under § 403.912(a)(1) since the effective date of the IFR.

List of Subjects**42 CFR Part 403**

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

Accordingly, as noted in section II. of this document, the Centers for Medicare & Medicaid Services is making the following correcting amendments to 42 CFR part 403:

PART 403—SPECIAL PROGRAMS AND PROJECTS

1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1395b–3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§403.912 [Amended]

2. Section 403.912 (a)(1) is amended by removing the phrase "not less than \$10,000, but not more than \$100,000" and adding in its place the phrase "not less than \$1,000, but not more than \$10,000."

Dated: August 17, 2017

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: September 6, 2017

Thomas E. Price,

Secretary,

Department of Health and Human Services.

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